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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,301	09/19/2003	Amanda April Hartley	12361-15US JEL	1515

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,301	HARTLEY ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,30-34,36-38,40 and 44-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *40 and 44-50* is/are allowed.

6)☒ Claim(s) *26, 30-34, 36-38 and 51-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and comments, received June 27, 2005, have been fully considered by the examiner. The following is a complete response to the June 27, 2005 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 26, 30, 31, 33, 34, 36-38 and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Jain (US 2002/0123749).

Jain discloses an electrosurgical device comprising an elongate member (26) having proximal and distal regions, the distal region (28) comprising a portion manufactured to have a desired curved shape (i.e. through steering). The examiner maintains that the tip would automatically be directed in a desired direction after perforating tissue when steered into a desired shape. The distal tip includes a plurality of electrodes for cutting tissue, as well as a pressure sensing mechanism for sensing pressure at a location in tissue (see Abstract and Para. [0019]). The pressure sensing mechanism includes a pressure transmitting lumen (central lumen of Figure 4) within the elongate member whereby a wire couples a pressure transducer (60) to a proximally located monitoring means. Similarly, a wire extends through the lumen to couple the electrode to a proximal energy source (Figure 4). A high frequency electrical energy source provides energy to the electrodes, and the device is releasably coupled to the power source and pressure monitoring system (see Figure 1).

With regard to claim 76, the examiner maintains that the Jain electrodes are equivalent to applicant "means for creating a void", particularly since applicant uses RF electrodes to create the void. Similarly, the "means for minimizing risk" of Jain is the steerable feature of the device and is deemed to be structurally equivalent to applicant's curved shape for minimizing risk of injury.

It is noted that the recitation in these rejected apparatus claims directed towards the use of the device to perforate tissue are deemed to not specifically limit the structure of the claims beyond the structure set forth in Jain. That is, applicant's structure basically includes a curved catheter with electrodes and a pressure sensing means, and no specific structure is recited to limit the structure based on the intended use of perforating tissue. The Jain device is deemed inherently capable of perforating tissue.

Claims 51-54, 56, 59, 60, 65-73 and 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by McGee et al (5,673,695).

McGee et al provide an RF electrode catheter device deemed inherently capable of perforating tissue. The device includes an elongate member having proximal (50) and distal (40) regions (Figure 5). The distal region includes a shape-memory section such that upon deployment, the distal region assumes a desired curved shape (col. 5, lines 48-66). A function tip includes a plurality of electrodes, and the distal portion remains in a straight configuration while located within sheath (54) and assumes the curved shape when unconstrained (see Figures 6 and 7). The distal region can assume a variety of shapes (Figures 2-7) including radial arcs of about 270 degrees.

With regard to applicant's claim 56, this claim is deemed to recite a limitation directed solely to the intended use of the device and does not substantively limit the structure of the claimed invention. The McGee et al device is deemed inherently capable of treating septal tissue in a heart.

The electrodes on the tip member may also be operated in a bipolar mode (see Abstract) and the size and use of a plurality of electrodes is disclosed by McGee et al. With regard to applicant's claim 71, the examiner maintains that any reasonable portion of the end of the device may be deemed the "distal portion". As such, the section labeled "40" in Figure 7 is deemed to show a substantially straight shape (with a more distal curve "42"). The device inherently includes a central lumen for housing the plurality of wires for the electrodes as is generally well known in the art.

Claims 51, 53, 54, 56-58, 76 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Swartz et al (5,814,028).

Swartz et al disclose an introducer device (Figures 4A-11C) that includes an elongate member having a functional tip (i.e. tapered, sharpened tip, see col. 12, lines 55+). The tip can deliver mechanical energy to tissue as it includes a tapered section for passing through an atrial septum. Each of the guiding introducers (i.e. elongate members) is provided with a manufactured curved shape to assume a desired orientation when deployed within the body. The guiding introducers are provided over a guidewire (i.e. constrained shape) and assume the curved configuration when the guidewire is then removed (i.e. unconstrained shape- see col. 18).

With regard to claim 76, the Swartz et al means for creating a void is the tapered distal tip which is deemed to be equivalent to the applicant's disclosed distal tip. Similarly, the Swartz et al means for minimizing risk to tissue is the pre-bent structure of the elongate member, which is again equivalent to applicant's disclose pre-bent structure.

Claims 51-53, 56, 59, 60, 65-69 and 71-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al (US 2002/0111618).

Stewart et al disclose various devices that include a preformed distal section inherently capable of perforating tissue. In particular, the device comprising an elongate member having proximal and distal regions, the distal region including a curved portion. The curved shape is assumed when the device is deployed from a sheath, such as sheath (200) in Figure 8. The various figures show numerous types of shapes. In particular, Figure 6 shows a shape that includes a distal portion (138) of the distal region having a substantially straight configuration, while the more proximal portion includes a curved portion. Stewart et al disclose various electrode arrangements on the distal sections, and the device inherently includes a lumen for housing the plurality of wires connected to the electrodes. Stewart et al also disclose a tapered distal section (Figure 6) where the outer diameter of the distal most portion is smaller than the outer diameter of the immediately adjacent portion (146).

Claim Rejections - 35 USC § 103

Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain ('749) in view of the teaching of Maguire et al (US 2002/0087156).

Jain, as addressed previously, discloses a catheter having a curved distal portion and a pressure sensing device thereon. Jain discloses a pressure transducer, and does not disclose the particular fluid-filled pressure sensing lumen as recited in applicant's claims 30-34.

Maguire et al, as addressed in the previous Office action, disclose another RF catheter device that includes a means to sense pressure at the distal end of the device. In particular, Maguire et al disclose the use of fluid pressure monitoring which includes a fluid-filled lumen to which a transducer is attached (see para. [0288]).

To have provided the Jain device with an alternative pressure monitoring system, such as taught by Maguire et al, to monitor the pressure at the end of the catheter device would have been an obvious design consideration for one of ordinary skill in the art at the time of applicant's invention.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al ('695) in view of the teaching of Racz et al (6,146,380).

McGee et al discloses various shapes for the distal portion of the elongate device, but fails to specifically disclose providing a marking means at the proximal end of the device to indicate the alignment of the curved distal portion.

Racz et al disclose another RF electrode device having a curved distal portion similar to the McGee et al device. In particular, Racz et al teach that it is advantageous to provide a marker means (48) at the proximal end of the device to indicate the orientation of the curved section (col. 5, lines 14-30).

To have provided the McGee et al system with a proximal marking to indicate the orientation of the curved distal portion would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Racz et al.

Claims 61-64 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al ('695) in view of the teachings of Jain ('749) and Maguire et al ('156).

McGee et al fail to provide a pressure sensing means at the distal end of the catheter.

The Jain device is substantially analogous to the McGee et al catheter and is structurally very similar. In particular, Jain teaches that it is advantageous to provide a pressure sensing means on a curved cardiac catheter device. Maguire et al further teach the specific use of a fluid-filled lumen as the pressure sensing means for an energy delivery catheter device.

To have provided the McGee et al device with a pressure sensing means to sense tissue pressure at the treatment site would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Jain, and it would have been further obvious to have used any well known pressure sensing system, including the fluid-filled sensor system taught by Maguire et al.

Allowable Subject Matter

Claims 40 and 44-50 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose the particular method of perforating a heart septum comprising the steps of applying energy to a perforation device, the perforation device having a manufactured curved shape, and advancing the tip of the perforation device such that the tip is automatically directed away from cardiac structures. While the prior art discloses several electrode device inserted through a heart septum (McGee et al, Swartz et al), the electrode devices that have the precurved shape are not used to perforate the septum. Rather, a guiding introducer having a substantially straight tip is used to perforate the septum prior to delivery of the catheter device through the perforation. It is noted that applicant's IDS of June 27, 2005 has cited various RF devices for perforating a septum. However, none of these devices include the particular curved distal portion that is automatically directed from tissue as recited in the instant application claims.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

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September 9, 2005